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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,408	07/16/2003	Shirlynn Chen	9/248	1543
28509	7590	08/26/2004	EXAMINER	
BOEHRINGER INGELHEIM CORPORATION 900 RIDGEURY ROAD P O BOX 368 RIDGEFIELD, CT 06877			WARD, EDWARD C	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/620,408	CHEN ET AL.
	Examiner	Art Unit
	Edward C Ward	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 June 2004.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-43 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-43 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>06041 c204</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

The amendment filed June 7, 2004 is acknowledged and has been entered. Claims 1-43 have been examined on the merits.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Llinas-Brunet et al., in view of Remington's Pharmaceutical Sciences guide (1995: including, e.g., the IDS citation therein -i.e., page 773, provided by Applicants; as well as pages 1510 and 1511 therein).

The instantly claimed invention is drawn to a pharmaceutical composition for treating hepatitis comprising the claimed tripeptide in combination with one or more pharmaceutically acceptable amines and one or more pharmaceutically acceptable oils.

Llinas-Brunet et al. teach a pharmaceutical composition containing the claimed tripeptide as well as a method for treating hepatitis using such a composition. Llinas-Brunet et al. further disclose that the pharmaceutical composition may contain any conventional non-toxic pharmaceutically acceptable carriers, adjuvants, or vehicles therein including those found in standard pharmaceutical texts such as Remington's Pharmaceutical Sciences (see entire document including claims). Llinas-Brunet et al. do not expressly teach including pharmaceutically acceptable amines and/or oils therein.

However, as evidenced by Remington's, oils such as vegetable oils and amines such as tromethamine (to name a few) are notoriously well known in the art to represent common well known pharmaceutically acceptable carriers, adjuvants, and/or vehicles routinely employed within the pharmaceutical art (see, e.g., page 773 and pages 1510-1511).

It would clearly have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add one or more oils and/or amines to the pharmaceutical tripeptide composition taught by Llinas-Brunet et al. because, as evidenced by Remington's, such agents are commonly employed in the pharmaceutical art for such purpose. Further, please note that the instant claims expressly recite "pharmaceutically acceptable amine or a mixture of pharmaceutically acceptable amines" and "one or more pharmaceutically acceptable oils, carriers, or solvents" [see (b) and (c) of claim 1]. Accordingly, based upon such recitations, Applicants are defining the type of amines and oils (as well as carriers and solvents) used within their claimed composition are those which are already recognized in the art as being "pharmaceutically acceptable".

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-79 of U.S. Patent No. 6,323,180 in view of Remington's Pharmaceutical Sciences guide (1995).

The instantly claimed invention is drawn to a pharmaceutical composition for treating hepatitis comprising the claimed tripeptide in combination with one or more pharmaceutically acceptable amines and one or more pharmaceutically acceptable oils.

The claimed invention of US '180 teach a pharmaceutical composition containing the claimed tripeptide as well as a method for treating hepatitis using such a composition, whereby the pharmaceutical composition comprises "a pharmaceutically acceptable carrier medium or auxillary agents" (see, e.g., claims 76-78). It should be noted that the teachings of US '180 disclose that the pharmaceutical composition may contain any conventional non-toxic pharmaceutically acceptable carriers, adjuvants, or vehicles therein including those found in standard pharmaceutical texts such as Remington's Pharmaceutical Sciences (see entire document including claims). The claimed invention of US '180 does not expressly teach including pharmaceutically acceptable amines and/or oils therein.

However, as evidenced by Remington's, oils such as vegetable oils and amines such as tromethamine (to name a few) are notoriously well known in the art to represent common well known pharmaceutically acceptable carriers, adjuvants, and/or vehicles routinely employed within the pharmaceutical art (see, e.g., page 773 and pages 1510-1511).

It would clearly have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add one or more oils and/or amines to the claimed pharmaceutical tripeptide composition taught by US '180 because, as evidenced by Remington's, such agents are commonly employed in the pharmaceutical art for such purpose. Further, please note that the instant claims expressly recite "pharmaceutically acceptable amine or a mixture of pharmaceutically acceptable amines" and "one or more pharmaceutically acceptable oils, carriers, or solvents" [see (b) and (c) of claim 1]. Accordingly, based upon such recitations, Applicants are defining the type of amines and oils (as well as carriers and solvents) used within their claimed composition are those which are already recognized in the art as being "pharmaceutically acceptable".

Thus, the invention as a whole is *prima facie* obvious, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to the examiner's supervisor, Bruce Campell, whose telephone number is (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CHRISTOPHER R. TATE  
PRIMARY EXAMINER